

REMARKS

In the Office Action, claims 1, 4, 7, 10, 13, 16, 19 and 22 are rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 5,514,655 ("*Dewille*"); and claims 1, 3, 5-7, 9, 11-13, 15, 17-19, 21, and 23-24 are rejected under 35 U.S.C. § 103 in view of *Dewille*. Claims 1, 2, 7, 8, 13, 14, 19 and 20 have been amended. Applicants believe that the rejections have been overcome in view of the amendments and for the reasons set forth below.

Of the pending claims, claims 1, 7, 13 and 19 are the sole independent claims. As amended, each recites, in part, a nutritional composition that includes a mixture of whey dietary protein hydrolysates and intact proteins. The whey dietary protein hydrolysates have a degree of hydrolysis that ranges from about 10% to less than 50% by weight and are in the form of a mixture of peptides and free amino acids wherein the free amino acids are present and in an amount of up to 20%. The intact proteins include, in part, bioactive proteins.

The nutritional compositions of the claimed invention provide very high nutrient needs for growth and development of non- or pre-mature gastro-intestinal tracts of young mammals. Further, the nutritional compositions as claimed can ensure optimal digestion and utilization (for tissue accretion) of the protein source and intends to minimize the nitrogen waste of the organism. Moreover, the protein mixture as claimed can provide a better source of amino acids to meet the general amino acid needs of the patient in addition to specifically favor maturation of individual organs. See, Specification, page 3, lines 4-10.

In particular, Applicants have discovered that the nutritional compositions with dietary protein hydrolysates that have a degree of hydrolysis of about 10% to about 15% can increase the relative weight of the liver as compared to free amino acid mixes. Further, hydrolysates with a degree of hydrolysis of about 15% to about 25% have been found to increase the concentration of protein, the relative weight, and the rate of protein synthesis in the jejunum as previously discussed. Moreover, highly hydrolyzed dietary protein (e.g., degree of hydrolysis greater than 25% or which contains more than 25% by weight of di- and tri- peptides, more preferably more than 30%) has been found to increase the rate of protein synthesis in the jejunum and the duodenum, particularly the duodenum as previously discussed.

In contrast, Applicants believe that *Dewille* is deficient with respect to the claimed invention. Indeed, the primary emphasis of *Dewille* relates to a nutritional product composed of

a soy protein hydrolysate as even suggested by the Patent Office. Further, *Dewille* merely discloses that the soy protein hydrolysate has a degree of hydrolysis in the range of 14% to 17% wherein the soy protein soy hydrolysate has less than 1% free amino acids. See, *Dewille*, column 3, lines 13-20.

This clearly contrasts a nutritional enteral composition that includes a mixture of whey dietary protein hydrolysates as claimed and discussed above. Indeed, Applicants have discovered that the nutritional compositions with whey protein hydrolysates that have varying degrees of hydrolysis as claimed can promote the growth and maturation of non-mature gastrointestinal tracts, including the jejunum and duodenum in young mammals as previously discussed. Therefore, Applicants do not believe that one skilled in the art would consider that *Dewille* discloses the claimed invention nor would be inclined to modify *Dewille* to practice the claimed invention.

Based on at least these differences, Applicants believe that *Dewille* fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that *Dewille* fails to anticipate and render obvious the claimed invention.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections be withdrawn.

In the Office Action, the Patent Office alleges that claims 2, 8, 14 and 20 fail to comply with 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 2, 8, 14 and 20 depend from claims 1, 7, 13, and 19, respectively. Further, each of claims 2, 8, 14 and 20 provides the limitation that the whey dietary protein hydrolysates contain at least about 5% of hydrolysate that has a degree of hydrolysis of about 40% and at least about 5% of hydrolysate that has a lesser degree of hydrolysis. In this regard, Applicants believe that the subject matter as defined by claims 2, 8, 14 and 20 further defines whey dietary protein hydrolysates that have a degree of hydrolysis in a range of from about 10% to less than 50% by weight as defined in independent claims 1, 8, 13 and 19. Therefore, Applicants believe that claims 2, 8, 14 and 20 comply with 37 C.F.R. § 1.75(c).

Accordingly, Applicants respectfully request that this objection to the claims be withdrawn.

Applicants note for the record that they have not received a copy of PTO-1449 with the Examiner's initial indicating that the references cited therein have been made of record during examination of the above-referenced patent application. The PTO-1449 form was filed by Applicants on September 12, 2001 along with the filing of the above-referenced application. Accordingly, Applicants kindly request a copy of the PTO-1449 form as discussed above.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of the same.

Respectfully submitted,

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